PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. §§1.136(a) and 1.17(a), a three month extension of the period for reply, i.e., to up to and including January 7, 2000 is respectfully requested. A check for $870.00 is enclosed in payment of the fee therefor. The Commissioner is hereby authorized to charge any additional required fee for this three month extension of time or any other fee occasioned by this paper, or credit any overpayment in such fees, to Deposit Account No. 50-0320.

REMARKS

Reconsideration and withdrawal of the objections to and rejections of this application are respectfully requested in view of the remarks herewith.

Claims 1 to 4, 6 to 10, 12 and 13 are now pending.

THE REJECTION OF ALL PENDING CLAIMS UNDER 35 U.S.C. § 103(a) AS BEING UNPATENTABLE OVER BERGSTROM ET AL IS OVERCOME

Claims 1 to 4, 6 to 10, 12 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Bergstrom et al. (US Patent No. 5,688,512).

Applicants wish to bring to the attention of Examiner Ryan a telephonic discussion that took place between Examiner Ryan, Examiner Housel and Mr. Kowalski. During that discussion the rejection of all pending claims under 35 U.S.C. 103(a) over Bergstrom et al. was addressed and an agreement was reached that this rejection would be withdrawn.

It was agreed that this rejection would be withdrawn based upon the lineage of the application in issue as it relates to U.S. patent No. 5,688,512 (Bergstrom et al.). U.S. Patent No. 5,688,512 issued from U.S. application Serial No. 08/375,993, filed January 20, 1995 as a

divisional of U.S. application Serial No. 08/079,601. U.S. application Serial No. 08/079,601 issued as U.S. Patent No. 5,523,089 on June 4, 1996. The present application was filed January 19, 1996. While the present application was copending with both U.S. applications Serial Nos. 08/079,601 and 08/375,993, there does not appear to be any need to claim priority from both of those applications. U.S. applications Serial Nos. 08/079,601 and 08/375,993 have the same specification (as the latter was a divisional of the former). The Declaration of Drs. Barbour and Luke establishes that the inventive entity of U.S. applications Serial Nos. 08/079,601 and 08/375,993 is not "another" as to the present inventive entity. And, Applicants only need start their lineage under Section 120 with a copending application; e.g., U.S. application Serial No. 08/079,601, and did not have to start their lineage with 08/375,993.

Accordingly, reconsideration and withdrawal of the rejection to claims 1 to 4, 6 to 10, 12 and 13 under 35 U.S.C. § 103(a) as being unpatentable over Bergstrom et al. (US Patent No. 5,688,512) are respectfully requested.

THE REJECTION OF ALL PENDING CLAIMS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH AS BEING INDEFINITE IS OVERCOME

Claims 1 to 4, 6 to 10, 12 and 13 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The basis for the Examiner's indefiniteness rejection rests on the phrase "substantially pure". In particular, the Office Action states that the term "substantially" is a broad term and therefore it is unclear what is encompassed by the term "substantially pure".

Applicants wish to bring to the attention of Examiner Ryan the same telephonic discussion referenced. During that interview the rejection of all pending claims under 35 U.S.C. 112, second paragraph was discussed and an agreement was reached that this rejection would be withdrawn.

It was agreed that this rejection would be withdrawn based upon the finding that the term "substantially pure" is in fact definite, as it is defined in the specification of U.S. Patent No. 5,688,512 (Bergstrom et al.), and it is used in the claims in the same manner as it is used in the claims of U.S. patent No. 5,688,512. In particular, the specification of U.S. Patent No. 5,688,512 (which is contained within the present application) defines the phrase "substantially pure" as follows:

> The polypeptides may be in a substantially pure form. In the present context, the term "substantially pure" is understood to mean that the polypeptide in question is substantially free from other components, e.g. other immunologically active components such as B. burdorferi cell wall and flagellar components. Preferably, the polypeptides are preferably free from B. burdorferi spirochete related components as such.

Also, *see In re Mattison*, 509 F.2d 563, 184 U.S.P.Q. 484 (C.C.P.A. 1975) (holding the use of the term "substantially" to be definite in view of the general guidelines contained in the specification). U.S. Patent 5,688,512 is incorporated by reference into the instant application and therefore the phrase "substantially pure" is also defined in the disclosure of the instant application. Furthermore, the term "substantially pure" is in the claims of U.S. Patent No. 5,688,512 and therefore the term is clear and definite for this reason too (as the PTO found the term clear and definite in so issuing that patent).

Accordingly, the phrase "substantially pure" is unquestionably clear and definite, and reconsideration and withdrawal of the rejection to claims 1 to 4, 6 to 10, 12 and 13 under 35 U.S.C. § 112, second paragraph as being indefinite are respectfully requested.

THE REJECTION OF ALL PENDING CLAIMS UNDER THE JUDICIALLY CREATED DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING IS OVERCOME

Claims 1 to 4, 6 to 10, 12 and 13 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 3 and 7 of U.S. patent No. 5,688,512. A finding of obviousness-type double patenting turns on whether the invention defined in a claim in the application in issue is an obvious variation of the invention defined in a claim in a prior patent. *See, e.g., In re Berg*, 46 U.S.P.Q.2d, 1226 (Fed. Cir. 1998). In order for an obviousness-type double patenting rejection to stand, the Examiner must show that the claims in issue are obvious based solely on the claims in the prior patent; the disclosure in the prior patent may not be used as prior art. Furthermore, any obvious-type double patenting rejection should make clear: (1) the differences defined by the conflicting claims; and, (2) the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent.

The pending claims in the instant application are directed to a method of inducing an immunological response by mucosally administering substantially pure OspA. The Examiner alleges these claims are obvious over claims 1 to 3 and claim 7 of U.S. patent No. 5,688,512. Claims 1 and 7 of the '512 patent are composition claims directed to a vaccine. There can be no double patenting between claims 1 and 7 of the '512 patent and the pending claims in the instant application because the former are directed to compositions while the latter are directed to

methods; inventions defined by compositions are patentably distinct from inventions defined by methods. Furthermore, there is nothing in claims 1 and 7 of the '512 patent that teaches or suggests mucosally administering substantially pure OspA to induce an immunological response.

Claim 3 of the '512 patent is directed to a protein. There can be no double patenting between claim 3 of the '512 patent and the pending claims in the instant application because the former is directed to a product while the latter are directed to methods; inventions defined by products are patentably distinct from inventions defined by methods. Furthermore, there is nothing in claim 3 of the '512 patent that teaches or suggests mucosally administering substantially pure OspA to induce an immunological response.

In summary, claims 1, 3 and 7 of U.S. patent 5,688,512 are patentably distinct from the claims of the instant application and therefore cannot be the basis for an obviousness-type double patenting rejection.

Claim 2 of the '512 patent is directed to a method of inducing a **protective** immunological response by administering substantially pure OspA; and while the administration can be by any route, no particular route of administration is specified in claim 2 of the '512 patent. Thus, there is nothing in the disclosure of claim 2 of the '512 patent that teaches or suggests **the particular mucosal administration** of substantially pure OspA to produce the **generalized** immunological response claimed in the instant application

As shown in diagram 1 immediately below, the commonality between these two methods (administration to elicit a protective immune response v. mucosal administration to elicit any immunological response) is minimal and one does not teach or suggest the other.

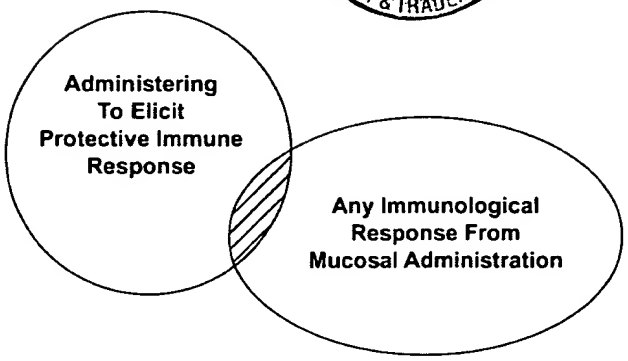


Diagram 1

More in particular, the present claims relate to a method for inducing an immunological response comprising **mucosally** administering a composition comprising substantially pure OspA; e.g., **orally** administering a composition comprising substantially pure OspA. The Office Action has failed to demonstrate how the generic claims of U.S. Patent No. 5,688,512, in and of themselves (since the specification of U.S. Patent No. 5,688,512 is unavailable to make the double patenting rejection) in any way particularly teach or suggest either mucosal administration or oral administration, or administration for inducing an immunological response as opposed to a protective immune response.

The fact that U.S. Patent No. 5,688,512 claims a method for inducing a protective immunological response comprising administering a vaccine comprising substantially pure OspA is of no moment. It is incumbent upon the Examiner to show how and why oral and mucosal administration are obvious from the generic recitation of "administering" in the claims of U.S. Patent No. 5,688,512. For instance, why and how from just the claims of U.S. Patent No. 5,688,512 should one select oral or mucosal administration as opposed to intradermal,

subcutaneous, intracutaneous, intramuscular, and all of the other ways one can "administer" substantially pure OspA, especially considering that the typical way a vaccine is administered is by injection, and not by oral or mucosal routes.

It is also incumbent upon the Examiner to show how and why oral and mucosal administration for any immunological response is obvious from the recitations of generically administering to achieve a protective immune response, again considering all the possible ways to administer an antigen, that injection is the typical route of administration, and a protective response is of different scope than an immunological response.

Having failed to so demonstrate, *inter alia*, why one should select oral or mucosal administration from all of the ways one can administer OspA based upon only the text of the claims of U.S. Patent No. 5,688,512, the obviousness-type double patenting rejection is fatally defective and cannot stand.

The fact that the claims of U.S. Patent No. 5,688,512 may dominate some embodiments of the present claims **is not controlling**. *In re Kaplan,* 229 U.S.P.Q. 678, 683 (Fed. Cir. 1986) ("**there must be some clear evidence to establish why the variation [between claims of a patent and of the application] would have been obvious [for double patenting rejection] which can properly qualify as 'prior art' ... if obviousness predicated on the level of skill in the art, prior art evidence is needed to show what that level of skill was**"; and **only claims of patent or patent application, not its disclosure, are available for use in double patenting rejection**).

Any dominance of the presently claimed subject matter by the claims of U.S. Patent No. 5,688,512 is not controlling in determining double patenting. *In re Kaplan*, 229 U.S.P.Q. at 681 ("**This commonplace situation [of one patent dominating another] is not, per se double**

patenting as the board seemed to think"). It is respectfully submitted that contrary to *In re Kaplan*, the Examiner is equating dominance with double patenting; and thus, the rejection is improper.

In further support of the proposition that U.S. Patent No. 5,688,512 can claim a genus which dominates some embodiments of the present claims while the present claims still remain patentably distinct, the Examiner is respectfully reminded that a species (or subgenus) may be patentably distinct from a genus such that a first patent issues to one party with claims directed to the genus, and a second patent issues to another party with claims directed to the species or subgenus. *See e.g., In re Baird,* 29 USPQ 2d 1550 (Fed. Cir. 1994); *In re Jones,* 21 USPQ 2d 1941 (Fed. Cir. 1992); *In re Taub, Wendler, and Slates,* 146 USPQ 384 (C.C.P.A. 1965); *In re Petering,* 133 USPQ 275 (C.C.P.A. 1962); *Hsing v. Myers,* 2 USPQ2d 1861 (BOPAI 1987).

The Commentary to Rules of Practice, 49 Fed. Reg. 48416, 48433 (Dec. 12, 1984), 1050 O.G. 395 (Jan. 29, 1985), corrected to 50 Fed. Reg. 23122 (May 31, 1985), 1059 O.G. 27 (Oct. 22, 1985), provides in pertinent part:

> Thus, if a species is patentable over a genus, the species is a "separate patentable invention" from the genus. Compare *In re Taub,* 348 F.2d 556, 146 USPQ 384 (C.C.P.A., 1965).

In this regard, the Examiner's attention is also directed to *In re Sasse,* 207 U.S.P.Q. 107 (C.C.P.A. 1980), wherein the Court of Customs and Patent Appeals held that a claim to a genus and a claim to a species within the genus are not claims to the same or substantially the same subject matter in the sense of 35 U.S.C. §135(b).

Essentially, if the present Applicants were strangers to the inventive entity of U.S. Patent No. 5,688,512 (but had the same effective filing date thereof of October 1988), the PTO would

not declare an interference between the present application and U.S. Patent No. 5,688,512 because the claims of the present application and of U.S. Patent No. 5,688,512 would be deemed patentably distinct: the claims of U.S. Patent No. 5,688,512 being directed to a particular genus; and the present claims being directed to a patentably distinct subgenus or species (especially since there is nothing in the art, as of the October 1988 effective filing date of the present application, in any way teaching or suggesting oral or mucosal administration of OspA). The fact that the genus claims of U.S. Patent No. 5,688,512 dominate some embodiments of the present claims is of no moment.

Accordingly, reconsideration and withdrawal of the rejection to claims 1 to 4, 6 to 10, 12 and 13 under the judicially created doctrine of obviousness-type double patenting are respectfully requested.

THE REJECTION OF ALL PENDING CLAIMS UNDER 35 U.S.C. § 103 AS OBVIOUS OVER BURGESS IS OVERCOME

Claims 1 to 4, 6 to 10, 12 and 13 stand rejected under 35 U.S.C. § 103 as obvious over Burgess. The Office Action states that a study described in Burgess teaches a method of orally administering *Borrelia burgdorferi* to animals. More specifically, the Office Action indicates that *Borrelia burdorferi* organisms that were identified with a monoclonal antibody specific for OspA were orally administered to mice, after which an immune response was elicited in these animals. Although the Office Action correctly points out the methodology of the study, Applicants respectfully disagree with the interpretation of this publication as it relates to the claims in the instant application. In particular, the Examiner fails to recognize and discuss the details and results of this experiment.

In the experiment described in Burgess (Burgess, pg. 236), a total of three mice were orally inoculated with 0.5 ml of culture media containing approximately 50 urine-cultured spirochetes per milliliter. There is nothing in this methodology that suggests a modification which would result in the pending claims in the instant invention. In particular, inoculation of three mice with urine-cultured spirochetes to demonstrate oral transmission of infection does not suggest a modification to oral administration of a substantially pure protein (OspA) to elicit an immunological response (note the above-quoted definition for "substantially pure").

It is significant to note that Burgess points out that "The development of *B. burgdorferi* antibodies in the mice orally inoculated with the urine cultured spirochetes indicates that the spirochetes were viable. It is unlikely that the spirochetes would have been absorbed into the blood through the gut had they not been alive." Burgess, pg. 240. Therefore, the reference upon which the Examiner relies for an obvious rejection particularly points out that transmission of infection via the oral route (and therefore the generation of an immunological response via oral inoculation) requires a viable agent. In contrast, the claims in issue define mucosally administering a substantially pure protein (OspA) that is not viable spirochetes. The requirement of a viable organism for oral inoculation in the Examiner's prior art reference in fact teaches away from mucosal administration of substantially pure OspA to elicit an immunological response

The Burgess publication must be considered as a whole if it is to be relied upon for an obviousness rejection under 35 U.S.C. § 103. *See W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (holding that a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention). Therefore, the results of the mouse study

cited in the Burgess publication must also be considered in addition to the methodology of the study relied upon by the Examiner. In this mouse study only two out of the three mice (67 %) developed antibodies by day 25 postinoculation; and, only one out of the three (33 %) had an antibody titer of 1:128 or greater, the level at which the author considered significant in the determination of a *Borrelia burgdorferi* infection. A significant antibody response in only 33% of the test animals does not suggest a successful outcome for oral inoculation of an animal.

Considering the Burgess publication as a whole, one finds nothing in this reference to suggest or motivate one skilled in the art to modify the reference to make the claimed invention of the instant application. Additionally, there is no reasonable expectation of success of the claims in the instant application based on a modification of the Burgess publication. The claims in issue teach oral administration of substantially pure OspA to produce an immunological response. Burgess states that for oral administration to produce an infection (an thus an immunological response), the agent must be viable; and the outcome is a significant antibody response in only 33% of the orally inoculated animals. Without motivation to modify and reasonable expectation of success, the Examiner has failed to make out a *prima facie* case of obviousness under 35 U.S.C. § 103.[1]

Accordingly, reconsideration and withdrawal of the rejection to claims 1 to 4, 6 to 10, 12 and 13 under 35 U.S.C. § 103 as being unpatentable over Burgess are respectfully requested.

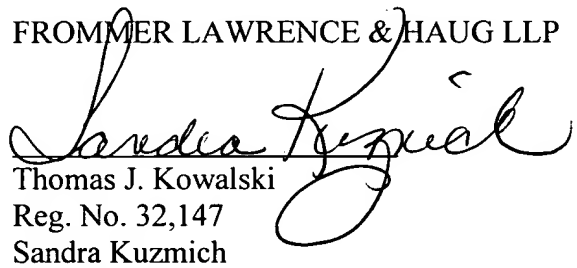
[1] Furthermore, Burgess' statement that the agent must be viable to produce an immunological response also demonstrates the impropriety of the double patenting rejection – one cannot select mucosal or oral administration from the generic language of the '512 patent claims without impermissible hindsight gleaned from the present application, as the prior art TEACHES AWAY FROM MUCOSAL OR ORAL ADMINISTRATION OF A SUBSTANTIALLY PURE PROTEIN SUCH AS OspA. Thus, in view of Burgess, the double patenting rejection especially fails and must be reconsidered and withdrawn.

CONCLUSION

In view of the remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. However, if any issue remains as an impediment to allowance, an interview with the Examiner and SPE Housel is respectfully requested prior to any Office Action issuing; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By: 

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